K991959

JAN - 6 2000

SECTION 6
510(k) SUMMARY

Submitter Name:	Pacific Surgical Innovations, Inc.
Submitter's Address:	360 Industrial Road San Carlos, CA 94070
Contact Person:	Terry Johnston, President
Phone Number:	650-802-6988
Facsimile Number:	650-802-0120
Date Prepared:	April 15, 1999
Device Trade Name:	PSI Titanium Aneurysm Clip
Device Common Name:	Aneurysm Clip
Classification Name:	Aneurysm Clip, 21 CFR 882.5200
Predicate Device:	Aesculap Titanium Aneurysm Clip (K983758) Taka Aneurysm Clip (K972750)
Device Description:	Bent titanium wire which provides a spring operated, self Closing aneurysm clip of various lengths/sizes.
Intended Use:	Placement in the intracranial space for the occlusion of a cerebral aneurysm (a balloon like sac formed on a blood vessel) to prevent it from bleeding or bursting. Placement of the clip requires the use of especially designed appliers
Technological Characteristics And Comparison to Predicate	The PSI Titanium Aneurysm Clip is manufactured from the same materials, to equivalent functional and dimensional specifications as the predicate clips. The material composition is titanium alloy (Ti-6Al-4V). The alloy composition and properties conform with ISO Standard 5832/3: "Implants for Surgery Metallinc Materials – Part 3: WroughtTitanium 6 – Aluminum 4 – Vanadium Alloy" and ASTM Standard F – 136: "Specification for Wrought Titanium 6AL-4V ELI Alloy for Surgical Applications". The PSI clips share similar tolerances, manufacturing controls, packaging and labeling as the predicate Taka clips.

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Performance Data:	When used with the appropriate clip applier, as with the predicate device, the PSI Titanium Aneurysm Clip functions in the same manner as the predicate device in the occlusion of cerebral aneurysms. When used in the MRI environment, the device presents no additional risk to the patient or other personnel, is compatible with current diagnostic imaging equipment and provides substantially reduced image artifacts over cobalt-based predicate clips.
Conclusion:	The Titanium Aneurysm Clip is safe and effective for it's intended use and meets all regulatory requirements to be found substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2000

Mr. Terry Johnston
Vice President and General Manager
Pacific Surgical Innovations, Inc.
360 Industrial Road, Unit H
San Carlos, California 94070

Re: K991959
Trade Name: Titanium Aneurysm Clip
Regulatory Class: II
Product Code: HCH
Dated: October 28, 1999
Received: November 1, 1999

Dear Mr. Johnston:

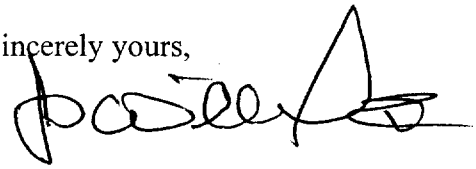
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 5

INDICATIONS FOR USE

Device Name: **PSI TITANIUM ANEURYSM CLIP**

Indication for Use: **Permanent placement in the brain for occlusion of cerebral aneurysms. They are only to be applied with PSI clip appliers with titanium alloy jaw inserts**

Prescription Use ___X___ OR Over the Counter _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991959